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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,663	03/14/2002	Nelson D. Horseman	AVI021	2987

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,663	HORSEMAN ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *108-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *108-151* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 March 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 108-151 are pending in the application.

This Office Action is in response to the Amendment filed on 4/27/05.

Response to Amendment

The rejection of claims 77-80, 83, 102-105 and 107 under 35 U.S.C.101 and 112 1st paragraph (scope of enablement) is moot in light of Applicant's cancellation of the claims.

The rejection of claims 50, 53-56, 58-61, 66, 69-75, 77-81, 87-107 under 35 U.S.C.112 1st paragraph (written description) is moot in light of Applicant's cancellation of the claims.

The rejection of claims 50, 53-56, 58-61, 66, 69-75, 77-81, 87-107 under 35 U.S.C.112 2nd paragraph is moot in light of Applicant's cancellation of the claims.

Claims 108-151 are rejected under 35 U.S.C.112 1st paragraph for same reasons as applied to claims 50, 53-56, 58-61, 66, 69-75, 77-81, 87-107 in the office action mailed on 1/25/05 and further discussed below.

Claims 142-145 are rejected under 35 U.S.C.112 2nd paragraph for reasons given below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 108-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the written description rejection applied to claims 50, 53-56, 58-61, 66, 69-75, 77-81, 87-107, Applicants argue that the claims include the functional limitation of "comprising a gene expression controlling region," such that the claimed nucleic acid molecules must be related to a gene expression controlling region. Applicants cite *In re Kaslow* to support the position of the compliance of the written description requirement is to determine whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession of the claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. Applicants further cite Ex parte Bandman and assert that the written description requirement is fulfilled for claims which are drawn to certain percent nucleotide sequence identities for defined nucleotide sequences. Applicants assert that in Bandman, the board find the claim "90% identical to polynucleotide sequence of SEQ ID NO:4" meets the written description requirement even without recitation of functional limitation. Applicants assert that since the pending claims not only include a reference nucleotide sequence of the claimed genus, but also a defined function which can be readily assayed, the claimed subject matter should satisfy the written description requirement. Furthermore, Applicants indicate that the specification discloses several pieces of DNA, including the 1.1kb fragment, have promoter activity. Applicants further assert that SEQ ID NO:2 (0.3kb), which is encompassed by the 0.5kb fragment that has high promoter activity, has been nominated as regulatory sequence involve tissue specific

expression of iFABP because it comprises a 14bp element of two direct 7bp repeats that is conserved among the promoters of several small intestine-specific genes in mammals, and two steroid hormone receptor are reported to binds to the iFABP promoter element. Moreover, Applicants argue that claiming nucleic acid molecules by hybridization is an accepted practice recognized in recent decisions of US Court of Appeals for Federal Circuit such as Enzo V Genprobe. Applicants assert since the present claims provide sequence information and functional requirement, it satisfies the written description requirement as set forth by Enzo V Genprobe. Further, Applicants argue that there is no requirement to specifically point out element/structure/sequence within a sequence required for promoter activity. Applicants assert the specification point out a TATA box like element and other putative gene expression controlling region can be readily identified by computer software program. Applicants argue that whether such element/structure/sequence contained within SEQ ID NO:1 or 2 were specifically identified is irrelevant as to whether applicant has possession of the invention as claimed. Applicants thus conclude that the claims meet the written description requirement.

The above arguments have been fully considered but deemed unpersuasive. The reasons for lack of written description support for the claimed subject matter were discussed in detail in the office action mailed on 1/25/05 (as applied to claims 50, 53-56, 58-61, 66, 69-75, 77-81, 87-107). It appears that Applicants misconstrue the reason for this rejection as being failing to disclose sufficient number of species of the claimed genus. As discussed in the previous office action, the analysis for the written description requirement is based on whether a representative number of species have been described by their complete structure and whether a representative number of species have been

sufficiently described by other relevant identifying characteristics. In view of the broad genus of the nucleic acid molecule as claimed, the instant specification fails to provide adequate description for a representative number of species by their complete structure and other identifying characteristics. The functional limitation of "comprising a gene expression controlling region" is not an adequate written description of the genus because it does not distinguish the genus from others except by function. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. A definition by function, does not suffice to define the genus because it is only an indication of what the nucleic acid molecule does, rather than what it is. With regard to Applicant's argument of Ex parte Bandman, Applicants are reminded that the situation is quite different wherein the specification of Bandman case provides an adequate support for the nucleotide sequences having sequence identity with an defined nucleotide sequence in the claims. In the Bandman case, the defined nucleotide sequence SEQ ID NO:4 encodes a glutamine fructose-6-phosphate amidotransferase, which is an enzyme that comprises known functional domain for its enzymatic activity. As such, the description of the structure aspects of the claimed nucleic acid is adequate because there is a link between structure and the function of the claimed invention. However, in the instant application, SEQ ID NO:1 is a 2.3 kb fragment 5' to chicken iFABP gene and SEQ ID NO:2 is a portion of SEQ ID NO:1 (0.3kb), wherein it is unclear whether such fragments have gene expression controlling function. As such, the structural and functional relationship between said fragments and the "gene expression controlling" function is missing. Similarly, the nucleic acid molecules having percent sequence identity with such fragments or its complement do not necessarily have "gene expression

controlling" function. The specification fails to describe the complete structure of the claimed genus of nucleotide sequences that is responsible for the "gene expression controlling" function. Therefore, the written description requirement is not satisfied.

With regard to Applicants' argument that the 1.1kb fragment has promoter activity, the examiner accepts that it may have modest activity based on the description of the specification. However, it does not provide adequate description to the claimed genus of nucleic acids because the specification fails to describe the structural limitation of the claimed genus, and which element/sequence of said fragment is responsible for the promoter activity (the structure responsible for the claimed function). With regard to Applicant's argument with regard to SEQ ID NO:2 having promoter activity, Applicants are reminded that having putative binding site within a sequence does not necessarily render the sequence having promoter activity. The art teaches that promoter region not only comprise transcriptional regulatory elements, but the other factors such as distance between those elements, secondary structure which affects the binding of the transcription factors are also important for the promoter function. Although the 0.5kb fragment comprising the fragment having the sequence of SEQ ID NO:2 has promoter activity, the fragment having sequence of SEQ ID NO:2 may not function as a proper promoter because the missing sequence may be necessary for the gene expression. Absent evidence from the contrary, the specification fails to provide adequate description for sequences having SEQ ID NO:2 or homology with SEQ ID NO:2 and its complement for having "gene expression controlling" function.

With regard to Applicant's argument of hybridization is an accepted practice for describing the claimed nucleic acid molecules, the examiner does not agree. Specifically,

the examiner does not agree with Applicant's interpretation of the case law of Enzo v Genprobe. Although the court's ruling is that "in the absence of sequence information for its hybridization site, a nucleic acid described only by its ability to hybridize with another DNA fails to meet the description of 112 1st", one cannot simply conclude that as long as the sequence information is given, the written description requirement is satisfied no matter what the claimed subject matter encompasses. As discussed above, the analysis for the written description requirement is based on whether a representative number of species have been described by their complete structure and whether a representative number of species have been sufficiently described by other relevant identifying characteristics. The claims are drawn to nucleic acid molecules comprising sequence that hybridizes under moderate condition to SEQ ID NO:1 and/or 2 and its complement, and having gene expression controlling function. The claimed genus encompasses large number of nucleic acid of various length and sequences (oligos as short as 10 base pair and large fragments of hundreds and thousands kilo base pair can all hybridize to SEQ ID NO:1 or 2 under moderated condition) which are not relate to each other. The specification fails to adequately describe what characteristic these nucleic acid molecule must share for their function as gene expression regulatory region. As such, the written description requirement is not met for this claimed genus of nucleic acid molecules.

With regard to Applicant's argument of disclosing element/structure/sequence within a sequence required for promoter activity is not necessary, the examiner's position is not that the specification has to provide such disclosure to satisfy the written description requirement. Rather, in view of the claimed genus of nucleic acid, the

specification must provide adequate description of structural features commonly possessed by members of the genus that distinguish them from others. The element/structure/sequence that links the claimed nucleic acid for its function is necessary for provide complete description of the structure of the claimed invention. Computer software may provide means for identification of such element, but it is not itself an adequate description of the structure of the claimed invention. Therefore, for reasons discussed in the previous office action and above, the written description requirement is not satisfied. This rejection is thus maintained.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 142-145 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 142, the word "derived" renders the claim indefinite because the nature and the number of derivative process is unknown. As such, the metes and bounds of the claim cannot be established.

Claims 143 recites the limitation "recombinant nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 138 does not recite a recombinant nucleic acid. Claims 144 and 145 depend on 143, therefore also indefinite because of this limitation.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELIAN QIAN
PATENT EXAMINER